Improving Quality One Child at a Time: Formal and Informal Feedback Loops Improve Determination of Capacity and Discussion During the Informed Consent Process
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Background: The Belmont Report highlights three fundamental ethical principles that form the foundation of clinical trials research – respect for persons, beneficence, and justice. The first two principles are core to the informed consent process and rely on the expectation of competence in adults. Minors are considered vulnerable because they may not have achieved the required competency. In deference to respect for persons and developing autonomy, parental permission and informed assent have replaced informed consent. Practices regarding the determination of capacity and the assent process vary amongst institutions. The purpose of this study is to explore current practice in our own institution, to determine capacity, and maximize the quality of the assent process.

Materials & Methods: A 60-minute focus group was conducted with a multidisciplinary group of clinical investigators using a semi-structured interview. The group included five pediatric oncologists and two certified oncology nurses. Textual data was categorized by the first author using directed qualitative analysis techniques. Major themes and subthemes were identified and representative quotes were selected.

Results: Key themes: 1. Acuity of the presenting illness often mandates a compressed time frame available to determine capacity and obtain affirmative assent. 2. Team meetings, informal individual team member, and family assessments provide feedback to the investigators to identify the child’s understanding and concerns so they can be addressed. 3. Feedback loops assisted the team in identifying and providing tools/strategies to help the child understand what is meant by research and the importance of assent process to their participation in clinical trials.

Conclusions: Feedback loops, common in the business world, allow service providers to better understand the needs of their customers and to effectively respond to their needs. Use of this strategy in the assent process of minors provides investigators with important information regarding a child’s knowledge, coping mechanisms, and support systems. This knowledge will assist investigators in making the important decision about capacity for assent to participate in clinical trials.